

Application No. 09/980,586
Supplemental Reply to Restriction Requirement mailed May 29, 2003

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-97: (Canceled)

98. (Previously Presented) A method for prophylactically or therapeutically treating Alzheimer's disease in a mammal comprising administering to the mammal a sufficient amount of a sterile aqueous suspension comprising at least 0.05 mg/ml of A β peptide in a regime effective to induce an immunogenic response comprising antibodies to the A β peptide, wherein the aqueous suspension is maintained at a physiologically acceptable pH and the suspension is prepared by adjusting the pH of an aqueous solution sufficient to solubilize said A β peptide; filtering the resulting suspension through a hydrophilic filter; and adjusting to a physiologically acceptable pH to form the aqueous suspension, and thereby prophylactically or therapeutically treat Alzheimer's disease in the mammal.

99. (Previously Presented) The method of claim 98, wherein the resulting suspension is maintained at a physiologically acceptable pH by use of about an effective amount of a pharmaceutically acceptable buffer.

100. (Previously Presented) The method of claim 98, wherein the A β peptide is a long form of A β peptide.

101. (Previously Presented) The method of claim 100, wherein said A β peptide is A β 42.

102. (Previously Presented) The method of claim 98, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

103. (Previously Presented) The method of claim 102, wherein the physiologically acceptable pH is maintained at a pH is about 5.5 to about 6.5.

Application, No. 09/980,586

Supplemental Reply to Restriction Requirement mailed May 29, 2003

104. (Previously Presented) The method of claim 99, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.

105. (Previously Presented) The method of claim 104, wherein the pharmaceutically acceptable buffer is an amino acid, salt and derivative thereof.

106. (Currently Amended) The method of claim 105, wherein the pharmaceutically acceptable buffer is ~~an amine acids, salts and derivatives thereof~~ glycine (sodium glycinate) or arginine (arginine hydrochloride).

107. (Previously Presented) The method of claim 104, wherein the pharmaceutically acceptable buffer is acetate (sodium acetate), or citrate (sodium citrate).

108. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension has an A_{β42} concentration of 0.1 to 0.8 mg/ml in a pharmaceutically effective buffer of 10 mM glycine, and the physiologically acceptable pH is maintained at a pH of about 5.5 to about 6.5.

109. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension further comprises sucrose.

110. (Previously Presented) The method of claim 109, wherein the amount of sucrose is sufficient to provide a 5% (w/v) sucrose suspension.

111. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension further comprises polysorbate 80.

112. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension is free of polysorbate 80.

Application. No. 09/980,586
Supplemental Reply to Restriction Requirement mailed May 29, 2003

113. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension further comprises a pharmaceutically acceptable adjuvant.

114. (Previously Presented) The method of claim 113, wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21 and alum.

115. (Previously Presented) The method of claim 114, wherein the adjuvant is QS-21.

116. (Previously Presented) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an A₆₄₂ concentration of at least 0.1, an effective amount of QS-21 and the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

117. (Previously Presented) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an A₆₄₂ concentration of 0.1 to 1.0 mg/ml in a pharmaceutically effective buffer of 10mM glycine, the adjuvant is at least 0.1 mg/ml of QS21, and the physiologically acceptable pH is maintained at a pH of about 6.

118. (Previously Presented) The method of claim 101, wherein the sterile aqueous suspension is a visually clear suspension further comprising an effective amount of DPPC (dipalmitoyl phosphatidyl chloride) and the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

119. (Previously Presented) The method of claim 118, wherein the sterile aqueous suspension has an A₆₄₂ concentration of at least 0.1 mg/ml and the physiologically acceptable pH is maintained at a pH of about 6.

120. (Previously Presented) The method of claim 98, wherein the method further comprises administering a pharmaceutically acceptable adjuvant separately or admixed in within the said sterile composition.

Application No. 09/980,586

Supplemental Reply to Restriction Requirement mailed May 29, 2003

121. (Previously Presented) The method of claim 113, wherein the sterile aqueous suspension is administered parentally.

122. (Previously Presented) The method of claim 98, wherein the sterile aqueous suspension is administered parentally.